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LESSONS FROM A DECADE OF TECHNICAL-SCIENTIFIC OPINIONS IN OBSTETRICAL LITIGATION

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INTRODUCTION

In recent years, we have been witnessing a growing number of cases of professional responsibility in the provision of health care, a trend which is followed by the specialty of Obstetrics/Gynecology.

With recent technological and clinical advances, the general public has acquired a high expectation of favorable results, and they consider that any deviation from this expectation must be someone's responsibility, usually the physician and/or staff who provided assistance. They do not take into account (nor it is released when there is media coverage of these cases) the individual biological variations or that technology itself has its limits.

As a result of these complaints, and facing the threat of professional liability cases, many doctors change their clinical attitude to a defensive medicine practice, whose exercise may not always be beneficial to the patient, by prescribing unnecessary exams or even by giving up or avoiding areas of activity more susceptible to litigation [1-16].

The knowledge that most health professionals have on this issue is the result the of America's circumstances dissemination, where the problem of Medical Liability is present in day-to-day professional routine and has dramatic consequences at the level of daily activity and on professional choices. It is a situation that exists for a few decades, that led to the escalation of insurance premiums which become a threaten to the obstetric practice [1-16].

In Europe, the awareness of the population to the possibility of medico-legal prosecution against doctors is a recent phenomenon, still with few studies on the topic. The same happens in Portugal, where there was little notion of the real scale of the problem, and of the possible consequences in professionals' daily clinical practice. In Portugal, although there

are some studies on Medical Liability in general and in other specialities, there has been none on Obstetrics in particular, besides the already developed by the author in 2007[17-19]. Then it was found that about half of obstetricians have already been involved in at least one case of Medical Liability. A similar proportion admitted to practice a positive defensive medicine, due to fear of medical liability processes, but 25% of specialists and 10% of interns also admitted to practice a negative defensive medicine [17,18].

Given that Obstetrics continues to be one of the worst hit areas in the international literature for medical liability processes and given their consequences in daily clinical practice, it seemed important to assess the Portuguese circumstances concerning situations of medico-legal dispute in Obstetrics, to evaluate the conclusions of technical-scientific opinions and analyze their consequences. To achieve this purpose we analyzed the Obstetrics cases examined in the Medico-legal Council since the creation of the National Institute of Legal Medicine and Forensic Sciences in 2001until 2011, which would be representative of the national situation concerning legal proceedings.

MATERIAL AND METHODS

Review and analysis of the cases of Medical Liability examined in the Medico-legal Council between 2001 and 2011, as well as their respective technical-scientific opinions. This analysis was carried out after formulating an application to consult the files to the President of the Directing Council of the National Institute of Legal Medicine and Forensic Sciences, which was accepted.

The analysis of this sample was performed by drawing a grid on which were recorded the reasons/causes that led to the establishment of cases, the sequence of events that culminated in the disputed event, the conclusion of technical-scientific opinions, the establishment of a causal link or a suggestion of violation of the 'leges artis'.

We performed a comprehensive characterization of the sample of medico-legal cases in obstetrics. All parameters were characterized by the determination of absolute frequencies and relative frequencies. The relative frequency of each cause for prosecution, each medical intervention that led to the complaint, the quality of the process and the result of expertise were determined per year. The annual change was graphed and the test of hypothesis of linear trend in relative frequency over the years, was performed using the chi-square test for trend. The association between each of the parameters of influence in medical intervention and each of the grounds of the complaints was evaluated by making use of the chi-square test. The level of significance used in this analysis was 5%. The statistical software SPSS ® v19.0.0.2 was used.

RESULTS

From a total 1261 cases analyzed in the period considered, 212 were selected regarding the specialty of Obstetrics/Gynecology. Of these 212 cases, 168 were related to Obstetrics – which represents the sample of our study – and 44 to Gynecology.

In obstetrics, the several causes found could be divided into 5 categories: perinatal asphyxia (fetal or neonatal death, permanent neurologic sequelae in the newborn), traumatic lesions in the newborn (result of instrumented delivery, breech vaginal delivery or shoulder dystocia), prenatal diagnosis/obstetric ultrasound, maternal sequelae (postpartum complications, including postpartum hemorrhage, postpartum hysterectomy, maternal mortality, surgical complications) and others (referring to all other situations not covered by the preceding groups). In the 168 cases analyzed, we found that the situations leading to prosecution were, in decreasing frequency order, perinatal asphyxia (50%), traumatic injuries of the newborn (24.4%), maternal sequelae (19%), prenatal diagnosis (5.4%) and other situations related to abortion and its treatment (1.2%). Medical interventions leading to the Obstetrics complaints analyzed can be grouped into lateness/absence in caesarean delivery (50%), no appraisal of complaints and/or exams (28%) and instrumentation of deliveries (22%). Further analysis on the causes and medical interventions that led to litigation are described elsewhere[20].

Regarding the quality of the clinical files sent for examination, we found reference to their poor quality in 89.5% of cases - 39.8% due to insufficient information, 36% due to the absence of data and 13.7% due to poor quality copies. In about 11% of cases, the technical-

scientific opinion was inconclusive due to the poor quality of the clinical process sent for analysis.

In cases reviewed, it was found that in 15.5% of their respective opinions, the role of the physician in question was not the most appropriate to the situation described, a trend that has been increasing over the years, p=0.011. The existence of a causal link appears suggested in 17.4% of opinions, a trend that has increased over the years, p=0.011. Both conclusions are mentioned as inconclusive in 10.6 and 11.2% of cases, respectively - Figure 1.

Regarding the distribution of these opinions we find that: in perinatal asphyxia a causal link was established in 21.4% of cases and was inconclusive in 15.5%. An infringement of the 'leges artis' was suggested in 20.2% of cases, with this conclusion being inconclusive in 16.7%. In traumatic lesions of the newborn, a causal link was established in 19.5% of cases and was inconclusive in 9.8%. An infringement of the 'leges artis' was suggested in 14.6% of cases with this conclusion being inconclusive in 12.2%. In maternal sequelae, a causal link was established in 15.6% of cases and inconclusive in 6.3%. An infringement of the 'leges artis' was suggested in 9.4% of cases with this conclusion being inconclusive in 6.3%. In prenatal diagnosis, a causal link was established in 11.1% of cases and was inconclusive in equal numbers. An infringement of the 'leges artis' was not suggested in any of the cases examined - Figure 2.

DISCUSSION/COMMENT

The sample selected seemed to meet the necessary conditions to analyze the proposed objective. In Portugal, it is for the Medico-legal Council to: exercise functions of technical and scientific advice; advise on technical and scientific expertise in the field of legal medicine and other forensic sciences issues; monitoring and evaluating expert activity developed in the National Institute of Legal Medicine and Forensic Sciences, proposing the most appropriate measures to the proper discharge of their duties and issuing optionally opinion on the necessary reforms of the national forensic expert system; deliver opinions to the models of cooperation of forensic expert services and other services or institutions; pronouncing, in its own initiative or at request of the chairman of the directive board on matters related to the tasks of the Institute; develop recommendations for the medical-legal and forensic activity; designate two personalities of recognized merit to the Ethics Committee. It is formed by: the chairman of the directive council of the National Institute of Legal Medicine and Forensic Sciences, the vice president and the vocals, a representative of the regional disciplinary boards of each regional section of the Medical Association, two university teachers of each of the scientific fields of clinical surgery, internal medicine, obstetrics and gynecology, and law; a university professor of each of the following scientific areas: pathology, ethics and/or medical law, orthopedics and traumatology, neurology, neurosurgery and psychiatry. When necessary, it may request the cooperation of teachers of other subjects or other higher education institutions as well as experts of recognized merit. The technical and scientific opinion can be requested by a member of the Government responsible for justice, by the Supreme Judicial Council, by the

Attorney General's Office or by the chairman of the directive council of the National Institute of Legal Medicine and Forensic Sciences.

Thus, for the evaluation of the national situation of Obstetrical Medical Liability cases, it seemed essential to review the cases referred to the Medico-legal Council, which with the creation of the National Institute of Legal Medicine and Forensic Sciences in 2001 brought together all national processes at its headquarters in Coimbra. Although it probably represents almost all judicial proceedings in the area of Medical Liability, it does not represent all proceedings in Civil and Disciplinary Law, which often are analyzed in another judicial place and not remitted to the Medico-legal Council. It probably represents the tip of the iceberg, but it indicates the Portuguese circumstances in this particular area. Moreover, gathering and analyzing the cases referred to the Disciplinary Council of the Medical Order, or even consulting those in courts not remitted to the Medico-legal Council, has proved to be an almost impossible task to accomplish retrospectively.

The annual caseload of Medical Liability in Obstetrics, although third in specialties most concerned by medico legal processes, did not have a significant linear trend over the years in accordance with the situation in the US and Canada[16]. We found that the most common causes of litigation in Obstetrics were perinatal asphyxia, traumatic injuries of the newborn (mostly related with instrumented deliveries, shoulder dystocia and vaginal delivery in breech presentation), maternal sequelae and prenatal diagnosis.

Is not for the Medico-legal Council to affirm of the existence of professional responsibility of the physician in the outcome of a particular clinical situation, but objectively answer the questions submitted to it. The assessment of any legally relevant liability will be the responsibility of the judicial authorities. Given that, in the technical-scientific opinions of files examined, the existence of a causal link was concluded in 17.4%, and the infringement

of the 'leges artis' appears suggested in 15.5% of cases, numbers which have grown significantly over the years and which were particularly relevant in the proceedings related to perinatal asphyxia and traumatic lesions of the newborn. Although these numbers are not so higher has those described for other specialties in Portugal, like general surgery, were in 23.9% of the cases was considered to exist violation of leges artis and in 44.8% a causal nexus was found between the medical practice and the alleged harm[19], in Obstetrics, the significant growing tendency found is worrying. Also very important is the fact that in 11% of cases, the opinion was inconclusive due to the poor quality of the clinical process sent for analysis. The knowledge of these data is important to alert doctors to improve the quality of medical files with sufficient and detailed information about all obstetrics procedures.

The growing tendency registered can influence the doctors daily practice has already described in other countries. Many doctors in this area manifest a great impact on their professional activity owing to Medical Liability lawsuits, most believing that this factor will shorten their careers[6]. Some studies have even demonstrated that such discontent is an important indicator of labour changes, patient dissatisfaction and non-adherence to treatment. According to Kravitz, 25-45% of obstetricians/gynecologists realized that, due to the constant threat of medico-legal cases, significant barriers exist to high quality care, which include insufficient time with patients, lack of clinical autonomy and an inability to take certain clinical decisions[11]. Among the factors that most contribute to a growing dissatisfaction among professional experts are management interference in clinical decisions, fear of litigation and the practice of defensive medicine, which can result in the abandonment of high-risk obstetrics[6]. Obstetric practice in the U.S. has declined in recent years not only because of fear of medico-legal processes, but also due to the desire for a more balanced lifestyle and more recently due to spiraling insurance premiums for medical claims[12,13]. Once aban-

doned, the probability of returning to it is less than 1%[13]. Another factor to consider is that obstetricians are increasingly restricted in their clinical judgement, decision making and behavior. In recent years, obstetric practice has evolved from a regional level to the national level, so that many protocols/performance lines are emitted, which must be reliable, practical and scientifically supported, since they have been used for many examples in court of guides for good clinical practice [4]. In 1990 a study by the American College of Obstetricians and Gynecologists (ACOG) revealed that about 75% of obstetricians had been sued at least once and 13% more than 3 times[8]. In 2003, 76% of ACOG members were sued at least once and the average was 2.6 times per member[4].

In Portugal, about half of the specialists have already been involved in at least one case of Medical Liability, and despite being significantly lower, the percentage of residents (9.8%) with previous involvement is also relevant. About 40% of Portuguese obstetricians with previous involvement in lawsuits refer to be influenced in daily clinical practice as a result of this involvement. This influence is reflected mainly by a positive defensive medicine, particularly in self-defense criteria in clinical decisions, systematic application of informed consent, better filling in of clinical processes, providing more information to the patient and requesting more diagnostic exams. Regardless of prior involvement in such lawsuits, about half of the Portuguese specialists consider that they are influenced by the fear of prosecution for Medical Liability, especially in deliveries and the emergency room. This influence is considered negative by most (67%) of the doctors concerned. Regarding negative defensive medicine, 25.2% of obstetricians would considered it by abandoning specific areas (the most cited being obstetric emergency and obstetric ultrasound)[17,18].

As recently concluded Pereira A. in his doctoral thesis, the current legal portuguese situation is not good for patients, who are rarely compensated for the injuries suffered nor for

physicians, often involved in processes that last for years. The situation is changing with more cases, more patients complaining and more convictions, but the doctors and patients need a more clearer system. The amount of compensations in Portugal have very large variations because there is no table, unlike France where there is a database with all claims in order to achieve greater equity, that can be consulter when the judge decide. In Portugal, judges read other judgments, but have great freedom to decide. In France were created conciliation systems that integrate judges and medical experts and Portugal should advance to a specialization within the courts or to the institutionalization of arbitration committees with judges and medical experts. The search for truth would be faster, which is important not only to protect the patient (for not waiting for several years), but also for the doctor. Usually the doctor is acquitted, but with five to ten years of uncertainty and trouble and much of the damage is caused by errors in hospitals complexity system. Most French complainants obtain a decision in four to six months with most (70 to 80%) having no reason and with the conclusion that the doctor did what he could - system with great gain since the patient goes to his life, do his grieving and the doctor is at peace. The Portuguese doctors have a sense of judicialization and risk above reality, because in practice there are not that many convictions, but he current situation is not good for patients (rarely compensated for their damage) nor for doctors because they are often involved in processes that last for years, start to be afraid and opt for defensive medicine[21].

These results highlight the impact that litigation can have on the professional activity and personal lives of obstetricians. It should alert them for the need to better complete medical clinical files in order to reduce or avoid medico-legal conflicts, as well as to the fact of increasing practice of defensive medicine and its consequences in daily clinical routine for doctors and patients.

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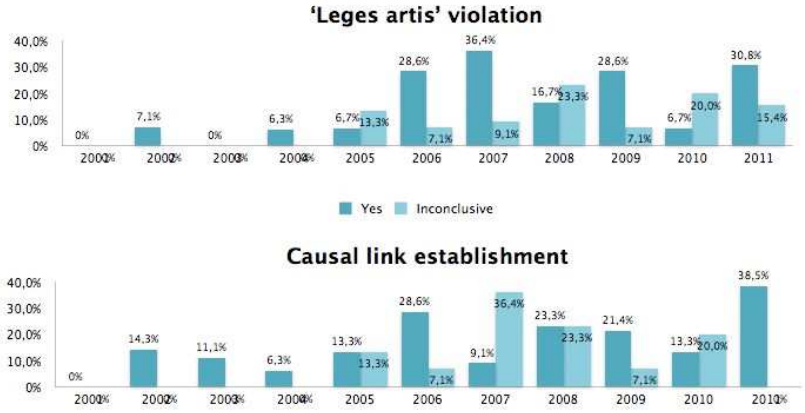

Figure 1 - Evolution of cases with suggestion of 'leges artis' violation or causal link establishment according to the years.

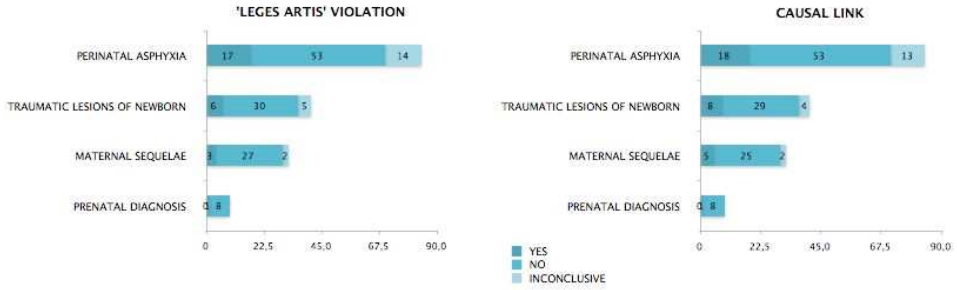

Figure 2 - Relation of the technical-scientific conclusions regarding 'leges artis' violation and causal link establishment according to the several motives of litigation.

Conflict of Interest Statement

Authors confirm that there are no known conflicts of interest associated with this publication and there has been no financial support for this work that could have influenced its outcome.

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